

THE UNITED STATES FOOD & DRUG ADMINISTRATION Overview of Regulatory Requirements Medical Devices



**Center for Devices and Radiological
Health**

Department of Health and Human Services

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Public Health Service
Surgeon General

National Institutes of Health

Health Resources and Services Administration

Agency for Health Care Research and Quality

Indian Health Service

Substance Abuse and Mental Health Administration

Centers for Disease Control

Food and Drug Administration

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Center for Devices & Radiological Health (CDRH)

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Center for Devices and Radiological Health (CDRH)

Daniel G. Schultz, M.D.
Director

Office of Compliance

Office of Science and
Engineering Laboratories

Office of Device Evaluation

Office of Surveillance
and Biometrics

Office of Communication,
Education and Radiation Programs

Office of In Vitro Diagnostic
Device Evaluation and Safety

FDA Authority to Regulate Federal Food Drug and Cosmetic Act (FD&C Act)

- **Medical Device Amendments**
 - May 28, 1976
- **Regulations implementing FD&C Act**
 - Title 21 Code of Federal Regulations (21CFR) Parts 800 - 1299

Definition of a Medical Device - Section 201(h) of the FD&C Act

- Diagnosis, cure, mitigation, treatment or prevention of disease or condition
- Affects the structure or function of the body
- Does not achieve intended use through chemical reaction
- Is not metabolized to achieve effect

There are a wide variety of medical devices regulated by the U.S. FDA...

- General Purpose Reagent
- Electrocardiograph
- Latex Patient Examination Glove
- Piston Syringe
- Endoscope
- Dental Floss
- Replacement Heart Valve

What is FDA's focus?

- Ensuring that medical devices are “reasonably” safe and effective.

Device Classification

- Classification determines extent of regulatory control (Risk Based)
- 1700 generic groups of devices
- Classified within 16 medical specialties
 - 21 CFR 862-892

862 = Chemistry/Toxicology

864 = Hematology/Pathology

866 = Immunology/Microbiology

868 = Anesthesiology

870 = Cardiovascular

872 = Dental

874 = Ear, Nose and Throat

876 = Gastro/Urology

878 = General Plastic Surgery

880 = General Hospital

882 = Neurological

884 = Obstetrical/Gynecological

886 = Ophthalmic

888 = Orthopedic

890 = Physical Medicine

892 = Radiology

Device Classification

- Regulation Number___880.5780
- Classification Name___Medical Support Stocking
- Product Code___FQL (**General Purpose**)
 - Class I EXEMPT from 510(k)
- Product Code___DWL (**Prevents Pooling of Blood**)
 - Class II and requires 510(k)

Classification System / Risk Categorization

	# Classified Devices	Risk
• Class I	782	Low
– <i>General Controls</i>		
• Class II	799	Medium
– <i>General Controls and</i>		
– <i>Special Controls</i>		
• Class III	119	High
– <i>General Controls</i>		
– <i>Premarket Approval</i>		

General Controls

- Adulteration / Misbranding
- Electronic Establishment Registration
- Electronic Device Listing
- Premarket Notification [510(k)]
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)

Special Controls

- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)

Establishment Registration & Medical Device Listing (21 CFR Part 807)

- Electronic Registration of Medical Device Establishment
 - Notification of U.S. Agent for Foreign Establishments
- Electronic Medical Device Listing
- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

Premarket Notification 510(k) (21 CFR Part 807)

- Marketing Clearance Process
- No form - Application submitted at least 90 days before marketing.
- Demonstration of Substantial Equivalence (SE) to legally marketed device in U.S.
- SE means “**As safe and as effective**”

510(k) Required When

- Marketing for First Time, or
- Significant Change to Existing Device

510(k) Exempt Devices - 798 / 47%

Class I 729 / 93%

Class II 69 / 9%

Changes to 510(k) Program

- Third Party Program (Accredited Persons)
- Special 510(k) - use of Design Controls to assure SE for device modifications
- Abbreviated 510(k) - Conformance with Recognized Standards to reduce data

510(k) Device User Fees

- For fiscal year 2009 (October 1, 2008 through September 30, 2009), the fee for a 510(k) review is the following in U.S. Dollars:
 - **Standard Fee** **\$3,693**
 - ***Small Business Fee** **\$1,847**
 - * (*≤\$100 million in gross receipts or sales*)

Premarket Approval (PMA) (21 CFR Part 814)

- Only applies to Class III devices
- Classification requires PMA
- Device found Not “SE” or “NSE”
- “New” - no basis for “SE”
- Proof of reasonable assurance of safety and effectiveness

PMA Device User Fees

“Original Application”

- For fiscal year 2009 (October 1, 2008 through September 30, 2009), the fee for a PMA review is the following in U.S. Dollars:
- **Standard Fee** **\$200,725**
- **Small Business Fee for First Application**
 - ***≤\$30 million in gross receipts or sales –***
.....Fee is Waived
 - ***≤\$100 million in gross receipts***
or sale -.....\$50,181

Investigational Device Exemption(IDE)

“Clinical Trials”

(21 CFR Part 812)

- Unapproved Devices
- Used on human subjects to collect safety and effectiveness data
- Protection of human subjects

Medical Device Labeling

(21CFR Part 801, 809, 812, 820)

- Any label or written material on the device or material that accompanies the device
- Labeling must provide adequate directions for use unless exempt
- Labeling must not be false or misleading

Quality System (QS) Regulation (21 CFR Part 820)

Quality Assurance System covering the design and manufacture of medical devices sold in the U.S.

- Similar to ISO 13485
- Standard for audit of device establishment

Medical Device Reporting (MDR)

“Adverse Event Reporting”

(21 CFR Part 803)

- Mechanism for FDA to identify and monitor significant adverse events involving medical devices

Events: Death, Serious Injury and Malfunction

Reported by: Manufacturer, User Facility, and Importers of medical devices

Postmarket Studies

- Post-approval Studies for Class III PMA devices.
- Section 522 Postmarket Surveillance Studies for Class II and Class III devices.

Medical Device Tracking

- Class II and III devices that:
 - Failure would reasonably have serious adverse health consequences;
 - Implanted in human body for more than one year; and
 - Life sustaining or Life supporting used outside a device user facility.
- e.g. Implantable pacemaker pulse generator and Continuous ventilator.

Food and Drug Administration Amendments Act of 2007 (FDAAA)

Medical Device Provisions

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

Fees Related to Medical Devices

“Existing”

- Premarket Applications (PMA, PDP, BLA, PMR)
- Panel-track PMA Supplements
- BLA Efficacy Supplements
- 180-Day PMA Supplements
- Real-time PMA Supplements
- 510(k) Premarket Notification

New Types of Fees

- Establishment Registration (*To account for 45% of User Fees*)
- 513(g) Request
- 30-Day Notice
- Periodic Reporting on a Class III Device

Small Business Determination

- Both domestic (U.S.) and foreign businesses may qualify as a small business starting in FY2008.
- Gross receipts or sales \$100 million or \$30 million for free/reduced PMA.
- U.S. firms (domestic) file using FDA-3602
- Foreign firms file using FDA-3602A
 - National Taxing Authority

Electronic Registration and Listing System

- Annual Registration Fee
 - Manufacturer
 - Single-use reprocessor
 - Specification developer
- \$1,851 U.S. Dollars for 2009
- No Discount for Small Business

Other Provisions

- Requires establishment of unique device identification system
- Streamlines Inspection by Accredited Persons
- Promotes development of pediatric devices
- FDAAA sunsets on October 01, 2012

CDRH Homepage

- <http://www.fda.gov/MedicalDevices/default.htm>
 - 510(k) Releasable Database
 - Device Classification Database
 - Device Advice
 - Register for “What’s New”
 - Guidance Documents
 - Much more...

Need Assistance?

Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

- <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>
- Email: DSMICA@FDA.HHS.GOV
- Fax: 240-276-3151
- Phone: 240-276-3150

